

Claims

1. Non-effervescent tablet for oral administration of sodium naproxen comprising a tablet core and, if desired, a sugar or film coat on the tablet core, wherein the tablet core consists of 30 to 99% by weight of sodium naproxen and 70 to 1% by weight of auxiliary agent component, comprising at least one basic auxiliary agent, based on the weight of the tablet core.
2. Tablet as claimed in claim 1, wherein the tablet core consists of 30 to 95% by weight of sodium naproxen and 70 to 5% by weight of auxiliary agent component, based on the weight of the tablet core.
3. Tablet as claimed in claim 1 or 2, wherein the tablet core consists of 60 to 95% by weight of sodium naproxen and 40 to 5% by weight of auxiliary agent component, based on the weight of the tablet core.
4. Tablet as claimed in any one of claims 1 to 3, wherein the tablet core consists of 70 to 93% by weight of sodium naproxen and 30 to 7% by weight of auxiliary agent component, based on the weight of the tablet core.
5. Tablet as claimed in any one of claims 1 to 4, wherein the sodium naproxen has a water content of 0.05 to 14% by weight.
6. Tablet as claimed in any one of claims 1 to 5, wherein the sodium naproxen has a water content of 6 to 12.5% by weight.

weight.

7. Tablet as claimed in any one of claims 1 to 6, wherein the auxiliary agent component comprises one or more basic auxiliary agents in a total quantity of at least 5% by weight, based on the weight of the tablet core.

8. Tablet as claimed in any one of claims 1 to 7, wherein the auxiliary agent component comprises one or more basic auxiliary agents in a total quantity of 10 to 30% by weight, based on the weight of the tablet core.

10 9. Tablet as claimed in any one of claims 1 to 8, wherein the auxiliary agent component comprises one or more basic auxiliary agents in a total quantity of 15 to 25% by weight, based on the weight of the tablet core.

10. Tablet as claimed in any one of the claims 1 to 9, 15 wherein the basic auxiliary agent is water soluble.

11. Tablet as claimed in any one of the claims 1 to 10, wherein the basic auxiliary agent is selected from basic alkali metal salts, basic alkaline earth metal salts, basic ammonium salts and basic amino acids.

20 12. Tablet as claimed in any one of claims 1 to 11, wherein the basic auxiliary agent is selected from sodium hydrogen carbonate, potassium hydrogen carbonate, sodium carbonate, potassium carbonate, trisodium citrate and trisodium phosphate.

25 13. Tablet as claimed in any one of claims 1 to 12, wherein

the basic auxiliary agent is selected from sodium hydrogen carbonate and potassium hydrogen carbonate.

14. Tablet as claimed in any one of claims 1 to 13, wherein the auxiliary agent component comprises one or more neutral 5 to weakly acidic fillers that improve the compressibility.

15. Tablet as claimed in any one of claims 1 to 14, wherein the auxiliary agent component comprises one or more water soluble, neutral to weakly acidic fillers that improve the compressibility.

10 16. Tablet as claimed in any one of claims 1 to 15, wherein the auxiliary agent component comprises one or more fillers, selected from sugars, hexoses, hydrolysed or enzymatically split starches, cyclodextrins, non-crosslinked polyvinylpyrrolidone, neutral to weakly acidic alkali metal 15 salts, neutral to weakly acidic alkaline earth metal salts, and neutral to weakly acidic ammonium salts.

17. Tablet as claimed in any one of claims 1 to 16, wherein the auxiliary agent component comprises one or more fillers, selected from hexoses, non-crosslinked polyvinylpyrrolidone, 20 maltodextrin and sodium chloride.

18. Tablet as claimed in any one of claims 1 to 17, wherein the auxiliary agent component comprises non-crosslinked polyvinylpyrrolidone as filler.

25 19. Tablet as claimed in any one of claims 1 to 18, wherein the auxiliary agent component comprises one or more non-water soluble fillers that improve the compressibility and the

tablet disintegration.

20. Tablet as claimed in any one of claims 1 to 19, wherein the auxiliary agent component comprises one or more fillers, selected from native and microcrystalline celluloses,

5 starches, modified starches, calcium phosphates and silicon oxide.

21. Tablet as claimed in any one of claims 14 to 20, wherein the proportion of filler is 1 to 50% by weight, based on the weight of the tablet core.

10 22. Tablet as claimed in any one of claims 14 to 21, wherein the proportion of filler is 3 to 30% by weight, based on the weight of the tablet core.

23. Tablet as claimed in any one of claims 14 to 22, wherein the proportion of filler is 10 to 25% by weight, based on the 15 weight of the tablet core.

24. Tablet as claimed in any one of claims 1 to 23, wherein the auxiliary agent component comprises at least one basic auxiliary agent, selected from sodium hydrogen carbonate and potassium hydrogen carbonate, and non-crosslinked polyvinylpyrrolidone as filler.

25. Tablet as claimed in any one of claims 1 to 24, wherein the auxiliary agent component comprises, based on the weight of the tablet core, 5 to 20% by weight of basic auxiliary agent, selected from sodium hydrogen carbonate and potassium hydrogen carbonate, and 5 to 20% by weight of non-crosslinked polyvinylpyrrolidone as filler.

26. Tablet as claimed in any one of claims 1 to 25, wherein the auxiliary agent component comprises a disintegrant.

27. Tablet as claimed in any one of claims 1 to 26, wherein the auxiliary agent component comprises a disintegrant
5 selected from croscarmellose, crospovidone and crosslinked sodium carboxymethyl starch.

28. Tablet as claimed in any one of claims 1 to 27, wherein the auxiliary agent component comprises one or more lubricants and/or glidants.

10 29. Tablet as claimed in any one of claims 1 to 25, wherein the tablet core does not contain any lubricant and does not contain any glidant.

30. Tablet as claimed in any one of claims 1 to 29, wherein the auxiliary agent component contains one or more ionic or
15 non-ionic tensides.

31. Tablet as claimed in any one of claims 1 to 30, wherein the auxiliary agent component contains one or more tensides, selected from sodium lauryl sulphate, sodium dodecyl sulphate, polysorbate and saccharose monopalmitate.

20 32. Tablet as claimed in claim 30 or 31, wherein the proportion of tenside is 0.1 to 5% by weight, based on the weight of the tablet core.

33. Tablet as claimed in any one of claims 1 to 32, wherein the tablet core consists of a granulate with a granular size
25 distribution from 0.25 to 1.25 mm.

34. Tablet as claimed in any one of the claims 1 to 33, wherein the hardness of the tablet core is at least 30 N.

35. Tablet as claimed in any one of the claims 1 to 34 with a content of sodium naproxen of 110 to 660 mg, based on the 5 water-free sodium naproxen.

36. Tablet as claimed in any one of the claims 1 to 13 and 33 to 35, wherein the tablet core consists of sodium naproxen and basic auxiliary agent.

37. Tablet as claimed in claim 1, comprising sodium 10 naproxen, sodium hydrogen carbonate, microcrystalline cellulose, croscarmellose, talc, and magnesium stearate.

38. Tablet as claimed in claim 37, comprising 50 to 60 % by weight of sodium naproxen, 15 to 25 % by weight of sodium hydrogen carbonate, 15 to 25 % by weight of microcrystalline 15 cellulose, 2 to 6 % by weight of croscarmellose, 1 to 5 % by weight of talc, and 0.5 to 2.2 % by weight of magnesium stearate.

39. Tablet as claimed in claim 37, comprising 55 to 65 % by weight of sodium naproxen, 10 to 25 % by weight of sodium 20 hydrogen carbonate, 2 to 15 % by weight of microcrystalline cellulose, 2 to 6 % by weight of croscarmellose, 1 to 5 % by weight of talc, and 0.5 to 2.2 % by weight of magnesium stearate.

40. Tablet as claimed in claim 39, comprising 55 to 65 % by 25 weight of sodium naproxen, 10 to 25 % by weight of sodium hydrogen carbonate, 5 to 10 % by weight of hydroxyl propyl

cellulose, 2 to 15 % by weight of microcrystalline cellulose, 2 to 6 % by weight of croscarmellose, 1 to 5 % by weight of talc, and 0.5 to 2.2 % by weight of magnesium stearate.

41. Process for producing a non-effervescent tablet for oral
5 administration of sodium naproxen comprising a tablet core
and, if desired, a sugar or film coat on the tablet core,
wherein the tablet core consists of 30 to 99% by weight
sodium naproxen and 70 to 1% by weight auxiliary agent
component, comprising at least one basic auxiliary agent,
10 based on the weight of the tablet core, characterized in that
a mixture the sodium naproxen and the auxiliary agent
component is compressed into the tablet cores and, if
desired, the tablet cores are coated with a sugar or film
coat.